WHO Technical Report Series
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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Fifty-second Report

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international requirements for the production and control of vaccines and other biologicals and the establishment of international biological reference materials. The report starts with a discussion of general issues brought to the Committee's attention and provides information on the status and development of reference materials for various antibodies, antigens, blood products and related substances, cytokines, growth factors, and endocrinological substances. The second part of the report, of particular relevance to manufacturers and national regulatory authorities, contains recommendations for the production and quality control of meningococcal group C conjugate vaccines, guidelines for regulatory expectations for clinical evaluation of vaccines, guidelines for the production and quality control of inactivated oral cholera vaccines and guidelines on viral inactivation and removal procedures intended to assure the viral safety of human blood plasma products.

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